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Published in:
Scandinavian Journal of Primary Health Care

DOI:
10.3109/02813432.2011.554271

Publication date:
2011

Document version
Publisher's PDF, also known as Version of record

Scandinavian Journal of Primary Health Care

ISSN: 0281-3432 (Print) 1502-7724 (Online) Journal homepage: http://www.tandfonline.com/loi/ipri20

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To cite this article: Sune Rubak, Annelli Sandbæk, Torsten Lauritzen, Knut Borch-Johnsen & Bo Christensen (2011) Effect of "motivational interviewing" on quality of care measures in screen detected type 2 diabetes patients: A one-year follow-up of an RCT, ADDITION Denmark, Scandinavian Journal of Primary Health Care, 29:2, 92-98, DOI: 10.3109/02813432.2011.554271

To link to this article: https://doi.org/10.3109/02813432.2011.554271

Published online: 09 Feb 2011.

Scandinavian Journal of Primary Health Care, 2011; 29: 92–98

informa
healthcare

ORIGINAL ARTICLE

Effect of "motivational interviewing" on quality of care measures in screen detected type 2 diabetes patients: A one-year follow-up of an RCT, ADDITION Denmark

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Abstract

Objective. "Motivational interviewing" (MI) has shown to be broadly applicable in the management of behavioural problems and diseases. Only a few studies have evaluated the effect of MI on type 2 diabetes treatment and none has explored the effect of MI on target-driven intensive treatment. *Methods.* Patients were cluster-randomized by GPs, who were randomized to training in MI or not. Both groups received training in target-driven intensive treatment of type 2 diabetes. The intervention consisted of a 1½-day residential course in MI with half-day follow-up twice during the first year. Blood samples, case record forms, national registry files, and validated questionnaires from patients were obtained. *Results.* After one year significantly improved metabolic status measured by HbA1c ($p < 0.01$) was achieved in both groups. There was no difference between groups. Medication adherence was close to 100% within both treatment groups. GPs in the intervention group did not use more than an average of 1.7 out of three possible MI consultations. *Conclusion.* The study found no effect of MI on metabolic status or on adherence of medication in people with screen detected type 2 diabetes. However, there was a significantly improved metabolic status and excellent medication adherence after one year within both study groups. An explanation may be that GPs in the control group may have taken up core elements of MI, and that GPs trained in MI used less than two out of three planned MI consultations. The five-year follow-up of this study will reveal whether MI has an effect over a longer period.

Key Words: *Alcohol abuse, blood pressure, Body Mass Index, motivational interviewing, type 2 diabetes*

Research regarding the intensive multi-factorial treatment of Type 2 diabetes patients has almost exclusively been conducted in the secondary health care system, in hospital settings [1,2]. A major problem in these studies has been poor patient adherence to healthy lifestyle and poor adherence to medication [1,2]. New approaches to achieve behavioural changes are therefore required. "Motivational interviewing" (MI) is one of the rather well-documented, scientifically tested methods of client counselling developed by Miller and Rollnick and it is viewed as a useful intervention strategy for changing behaviour and improving disease management [3]. MI has been used in very few studies of type 2 diabetes and the results have been varying [4–8]. People with type 2 diabetes in Denmark are primarily treated in the primary health care system. No investigations have evaluated the effect of MI in relation to target-driven intensive treatment of people with type 2 diabetes detected by screening in primary care. The aim of this study is to evaluate whether a course in MI for general practitioners (GPs) improves patient adherence to intensive treatment based on risk parameters and adherence to prescribed medication in people with type 2 diabetes detected by screening.

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(Received 23 August 2009; accepted 21 December 2010)

ISSN 0281-3432 print/ISSN 1502-7724 online © 2011 Informa Healthcare
DOI: 10.3109/02813432.2011.554271

Previous studies show a significant effect of "motivational interviewing (MI)" in a broad area of diseases through changing patients' self-efficacy in terms of their understanding of the disease, their beliefs regarding treatment and prevention aspects, and their motivation for changing behaviour.

- This study shows significantly improved metabolic status after one year in people with screen-detected type 2 diabetes regardless of whether they received MI. Specific reasons for not achieving an effect of MI are discussed.
- Important factors for a lacking effect may be the fact that GPs in the control group have taken up some of the core concepts of MI and that GPs trained in MI used less than two out of three planned MI consultations.

Material and methods

Study group

This randomized controlled trial is a sub-study of the ADDITION study [9], which is a multi-centre randomized controlled trial of a target-driven approach to intensive treatment of 40- to 69-year-old people with screen-detected type 2 diabetes. Inclusion and exclusion criteria followed the ADDITION study [9]. All patients newly diagnosed with type 2 diabetes in the screening study were eligible to participate, unless they were found to have: contraindications or intolerance to study medication; a history of alcoholism, drug abuse, psychosis, or other emotional problems likely to invalidate informed consent or adherence to treatment; malignant disease with a poor prognosis; were pregnant or lactating.

This study included practices/GPs from the intensive arm of ADDITION Denmark from two counties in DK (Figure 1) randomized by the project manager using the method "drawing lots" into *an intervention group (I-group)* comprising GPs who completed an MI training course and *a control group (C-group)* of GPs who received no formal training in MI. Randomization was stratified by county, size of practices, and by numbers of full-time GPs.

In order to determine sample size, a power analysis was performed [10]. The inclusion and dropout of the GPs and patients are shown in the flowchart, Figure 1.

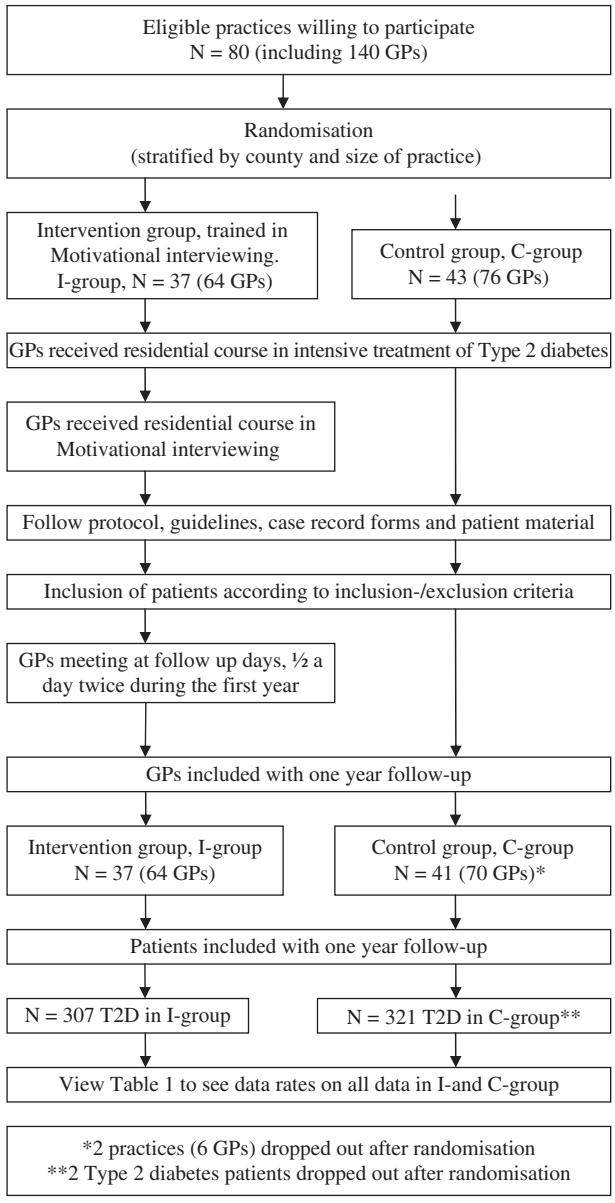

Figure 1. Flowchart of included general practitioners (GPs) and screen-detected type 2 diabetes patients (T2D)

Method of intervention

The courses in "motivational interviewing" (MI) for the GPs in the I-group were conducted by a trained teacher introducing a manual [11] which together with "Motivational interviewing, preparing people to change addictive behaviour" [3] constituted the theoretical part of the course curriculum. The I-group was coached in the key points of MI [3]. The training also included the use of specific skills, e.g. empowerment [12], ambivalence [3], the decisional balance schedule [3], the visual analogue scale [3], stage of change [13], and reflective listening [3], all of which are described in detail in the book MI [3]. The I-group courses consisted of a 1½-day training sessions with a half-day follow-up twice during the first year. None of the GPs in I- and C-group had previously participated in an MI course. All GPs in the I- and the C-group participated in

the same half-day course on intensive treatment of type 2 diabetes. During these diabetes training sessions, it was stressed that GPs should act as counsellors for the patients, allowing treatment decisions to be based on mutual understanding between the patient and the GP. In Denmark, GPs' consultation encounters average 15 minutes and the County Health Insurance has agreed to one longer preventive consultation encounter of 45 minutes per patient. In this study the County Health Insurance agreed to allow the GPs in the I- and C-group to undertake three consultations of 45 minutes per patient, in which the I-group could use MI.

Measurements

The intervention phase began on 1 May 2001. The study was based on the following data obtained at baseline and one-year follow-up:

Risk profile. HbA1c was analysed using a BioRad Variant ^{TM} and serum cholesterol/HDL-cholesterol/triglycerides were analysed using a Hitachi 912. LDL-cholesterol was calculated using Fridewald's formula. All blood samples were analysed according to the Danish quality assurance for laboratories.

Height was measured to the nearest 0.1 cm using a fixed rigid stadiometer. Participants' weight in light indoor clothing was measured to the nearest 0.1 kg with a SECA scale. Blood pressure (systolic and diastolic) was measured at rest at the GP's surgery.

Health care services. Prescribed medication was reported by the GPs on case record forms. The number of prescriptions cashed in at the pharmacy by the patient was drawn from the National Health Service Registry. The number of encounters and blood samples was obtained from register data files from the National Health Service Registry.

Self-reported data. Data on smoking and exercise in leisure time and at work were obtained from patient questionnaires.

- The questions on physical activity had previously been validated in the "International Physical Activity Questionnaire (IPAQ)" [14].
- The questions on smoking had previously been validated in the "Summary of Diabetes Self-Care Activities" (SDSCA) questionnaire [15,16].

Answer categories for the questions were dichotomized (yes/no) or presented on continuous scales ("On how many of the last 7 days did you ...?"). The questionnaires were designed and processed in Teleform.

Overall endpoints are described in detail in the ADDITION study [9], from which this study included the "intermediate endpoints" and "process-of-care endpoints".

Statistical methods

Statistical analysis of data was conducted in SPSS. Results are either given as median and range, as simple percentages, or as mean and 95% confidence interval (CI). A paired t-test was used to compare changes from 0 to 12 months. A statistical significance level of 0.05 (two tailed) was used. A non-parametric Mann–Whitney test was used for variables not distributed by normal variation. The clustering within GPs was adjusted for by using a mixed regression model assuming random variation between and within GPs. The power calculation took into account the cluster design with ICC for the outcomes of 0.05, which is a conservative estimate for intermediate outcomes in primary health care. In the power analysis SPSS Sample Power Two Sample Proportion was used. After correction of cluster sampling it was concluded at that time that the study would show effect (95% CI) of "motivational interviewing", if a minimum 19% of patients reached normal HbA1c (HbA1c below 6.4).

Results

A flowchart for participating practices (GPs) and patients can be seen in Figure 1. In all, 80 practices (140 GPs) were included. The 37 practices (64 GPs) were randomized into the I-group and 43 practices (76 GPs) into the C-group. Two practices (six GPs) and two patients dropped out after randomization. All GPs in the I-group participated in the educational and training courses, and less than 10% were absent from the half-day follow-up meetings. The study included: 628 type 2 diabetes patients with a one-year follow-up, 321 in the C-group and 307 in the I-group. Among the 628 patients, 58% were male; average age was 61 years with no significant differences between the groups. The response rate to the patient questionnaire was 87% in the I-group and 90% in the C-group. According to the case record forms, 78% of patients in the I-group and 75% in the C-group had visited their GP one year after their inclusion in the study. Blood sample results were obtained from all patients.

Measures for the risk profile at 0 and 12 months are presented in Table I. The number of patients within the treatment targets and BMI < 27 at study entry and after one year is seen in Table II. A statistically significant improvement regarding blood pressure, blood lipid measurements, HbA1c, and BMI is seen in both groups from 0 to 12 months with no significance differences between study groups. Table II also shows the patients' use of health care services in general practice within one year, i.e. number of consultations, blood samples etc. with no significant differences between study groups.

Table I. Risk profile measures at 0- and 12-month follow-up.

	Total values						p-value
Value Group	I-group (n = 307)			C-group (n = 321)			I- vs. C-group (n = 307/321)
Time (months)	n/n total	0 mean	Δ 0–12 mean	n	0 mean	Δ 0–12 Mean	Time 0–12
Systolic BP	240/307	140.3	–6.4*	240/321	138.9	–5.8*	ns
Diastolic BP	240/307	83.6	–3.8*	240/321	82.7	–3.4*	ns
T-Chol (blood total cholesterol (mmol/l))	307/307	5.5	–0.9*	321/321	5.5	–0.9*	ns
HDL (high-density lipoproteins (mmol/l))	307/307	1.3	0.1*	321/321	1.3	0.1*	ns
LDL (low-density lipoproteins (mmol/l))	307/307	3.1	–0.6*	321/321	3.2	–0.7*	ns
Tgly (triglyceride (mmol/l))	307/307	1.9	–0.3*	321/321	2.2	–0.3*	ns
HbA1c (% GHb)	307/307	6.9	–0.7*	321/321	6.8	–0.7*	ns
BMI (Body Mass Index)	230/307	30.5	–0.8*	238/321	30.8	–0.9*	ns
% Number of non-smokers	270/307	66.1	6.6	276/321	71.2	7.8	ns
Number of days per week with hard physical activity (example: aerobics)	264/307	3.3	0.9	276/321	3.5	0.5	ns
Number of days per week with moderate physical activity (example: bicycling in moderate tempo)	264/307	4.2	0.6	276/321	3.8	0.7	ns

Notes: *$p < 0.01$. ns = no statistically significant difference.

The ratios between the proportion of patients reported by GPs to have had a prescription for blood glucose lowering drugs, BP or lipid lowering drugs, and the proportion of patients registered to have "cashed in" a prescription for each of the three treatments at the pharmacy did not differ statistically significantly, either within or between the I- or the C-group (Table III).

Discussion

Statement of principal findings

The study showed at one-year follow-up no effect of MI on the risk profile of patients with type 2 diabetes detected by screening. However, significant changes in patient outcome including improved metabolic status were demonstrated after one year within both treatment groups. An explanation of lack of difference may be that GPs in the control group may have taken up core elements of MI, and that GPs in the intervention group used less than two out of three planned MI consultations.

Strengths and weaknesses of the study

The validity of the study is strong by virtue of (1) the attendance of all GPs on courses intended for each group, (2) the absence of less than 10% of GPs from the follow-up meetings, (3) a patient response rate to the questionnaire exceeding 87%, (4) acquisition of 78% of the case record forms from GPs in the I-group and 75% from GPs in the C-group, and (5) acquisition of a 100% data rate from the National Health Service Registry and a 100% data rate of blood samples.

We cluster randomized at practice level and included enough practices to ensure similar distributions in study groups, and used stratified randomization of GPs on size of practice and on county in order to obtain high internal validity and a low degree of selection bias. This study may suffer from a limitation because training in MI was performed by only one person. This makes outcome highly dependent on this person's teaching methods and capacity to train the GPs [5]. We evaluated the course and found GPs in the I-group adhered more to the methods of MI than GPs in the C-group [5].

Strength and weakness in relation to other studies, meaning of the study, unanswered questions

Adherence to prescribed medication was high compared with previous studies [17–19] despite intensive poly-pharmacological treatment. No significant differences between the groups were found, however. This may be the result of the intensive training of GPs in both groups in treatment of type 2 diabetes, stressing the importance of GPs acting as counsellors. This hypothesis is supported by a previous paper from this study on how MI influences GPs' professional behaviour [5]. In summary the effect of MI may have been reduced because GPs in the C-group had a greater awareness of all aspects of type 2 diabetes treatment, including motivating lifestyle changes. The lacking effect of MI may also be ascribed to the fact that GPs trained in MI used less than two out of three planned MI consultations.

The results revealed that a large proportion of the patients in both groups had values (e.g. HbA1c, lipid-profile, blood pressure, or BMI) that were, in

Table II. Patients below treatment target and BMI <27 after one year/patients' use of health care services in general practice within one year.

	Achieved treatment goal at time 0 months		p-value
Time Group	I-group (n = 307) % of total n	C-group (n = 321) % of total n	I- vs C-group Time 0 months
SBT	39%	44%	ns
DBT	59%	66%	ns
Cholesterol	21%	23%	ns
HbA1c	66%	69%	ns
BMI	21%	25%	ns
	Achieved treatment goal at time 12 months		I- vs C-group Time 12 months
SBT	45%	47%	ns
DBT	59%	62%	ns
Cholesterol	49%	49%	ns
HbA1c	83%	82%	ns
BMI	20%	24%	ns
	Patients' use of health care services in general practice within one year		
Group	I-group	C-group	p-value
No. ordinary consultation*	6.5 (1.0–20.0)	6.0 (1.0–14.0)	ns
No. preventive consultation*	1.5 (1.0–2.0)	1.0 (1.0–1.0)	ns
No. telephone consultation	5.5 (1.0–12.0)	8.0 (1.0–27.0)	ns
No. blood samples**	3.7	4.5	ns
No. blood glucose**	4.3	6.7	ns

Notes: ns = no statistical significant difference, $p < 0.05$. *median (range) number consultations per patient per GP; **mean number telephone consultations per patient per GP. Study treatment targets: SBT ≤ 135 (systolic blood pressure (mmHg)); SBT ≤ 85 (diastolic blood pressure (mmHg)); T-chol ≤ 5.0 (blood total cholesterol (mmol/l)); HbA1c ≤ 6.4 (% Glycolated Hb); BMI ≤ 27 (Body Mass Index).

fact, within the treatment goals from the beginning of the study. This left only little room for demonstrating an effect of MI due to the narrowness of the intervention field.

Implications for future research or clinical practice

Previous studies using MI in general practice have demonstrated MI to be effective [8,20–24]. However, only a few studies have focused on how to implement MI in the daily clinical work in general practice in such a way that it is ascertained that the method is used after study closure [25,26]. They concluded that it was possible to implement the use of MI in general practice although barriers existed [5,25,26].

We have previously shown [10] that (1) an MI course seemed to influence GPs' professional behaviour, (2) GPs reported that they used MI in their daily practice, and (3) that patients changed contemplation of behaviour [5,6]. The lacking effect of MI on risk profile in this study may be a result of the study's attempt to accomplish too much over too short a period.

Two recent meta-analyses concluded that psychological therapies improve long-term glycaemic control, and that MI had an effect on lifestyle factors such as food intake, smoking, alcohol consumption, and medication adherence [4,27]. These meta-analyses as well as the results from this study [4–6] indicate a need for long-term evaluation of the effect of MI on the risk profile.

Table III. Adherence to prescribed medication: Prescriptions "cashed in" by patients at the pharmacy compared with prescriptions registered by the GPs after one year (% of patients).

	I-group (n = 307)		C-group (n = 321)		
Medicine % of patients in group	%*	% ratio	%*	% ratio	I- vs C-group p-value
Anti-hypertensives	64%/64%	1	63%/63%	1	ns
Lipid-lowering medication	43%/43%	1	47%/47%	1	ns
Anti-thrombotics	54%/64%	0.84	56%/63%	0.88	ns
Oral anti-diabetics	37%/39%	0.96	36%/36%	1	ns

Notes: ns = no statistical significant difference, $p < 0.05$. *X% of patients cashed in a prescription for medication/Y% of patients had registered a prescription for medication from the GP.

Conclusion

The study showed at one-year follow-up no effect of MI on the risk profile of patients with type 2 diabetes detected by screening. However, significant changes in patient outcome including improved metabolic status and medication adherence were demonstrated after one year within both treatment groups. An explanation may be that GPs in the control group may have taken up core elements of MI, and that GPs in the intervention group used less than two out of three planned MI consultations. Whether more intensive training of GPs in MI and whether closer contact between the GPs and patients are needed require new studies.

Research ethical aspects

The study was approved by the Committee on Biomedical Research Ethics and by the Danish Data Protection Agency according to conducting the study within the rules of data safety and research ethics. The authors confirm that all patient/personal identifiers have been removed or disguised so that the patient/person(s) described are not identifiable and cannot be identified through the details of the story. The paper conforms to the Consort statement.

The unique trial number and the name of the registry: ClinicalTrials.gov Identifier: NCT00237549.

Funding body

The ADDITION trial was supported by the National Health Services in the counties of Copenhagen, Aarhus, Ringkoebing, Ribe and South Jutland in Denmark, Danish Research Foundation for General Practice, Danish Centre for Evaluation and Health Technology Assessment, the Diabetes Fund of the National Board of Health, the Danish Medical Research Council, the Danish Medical Association Research Fund, the Diabetes Association's Foundation for Scientific Research, the Aarhus University Research Foundation, and Novo Nordisk Foundation. Furthermore the trial has been given unrestricted grants from Novo Nordisk AS, Novo Nordisk Scandinavia AB, ASTRA Denmark, Pfizer Denmark, GlaxoSmithKline Pharma Denmark, SERVIER Denmark A/S, and HemoCue Denmark A/S.

Competing interests

No author of this paper has any competing interests.

Acknowledgement

The authors would like to thank all patients and GPs involved in the ADDITION study, Carl Erik Mabeck, professor, DMedSci, for training GPs in "motivational interviewing", and the staff at the Department of General Practice, University of Aarhus, for help during the study.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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